



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Wolfgang-Reinhold Knappe

Serial No. 09/426,931

Filed October 22, 1999

SPREADING LAYERS, WETTING AGENTS
FOR THEIR PRODUCTION AND
THEIR USE IN TEST STRIPS

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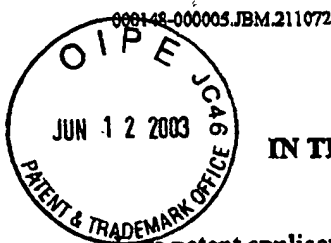
SUBMISSION OF DECLARATION UNDER 35 CFR §1.132

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Please consider the following Declaration of Dr. Knappe. In addition, please provide any extensions of time that may be necessary and deposit any overpayments and charge any fees that may be due to Deposit Account 23-3030 but do not include any payment of issue fees that are or may become due.

<p>I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, Alexandria, VA 22313-1450 on <u>June 10, 2003</u></p> <p>_____ James B. Myers, Jr. Name of Registered Representative</p> <p>_____ <i>James B. Myers Jr</i> Signature</p>
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DECLARATION OF DR. KNAPPE SUBMITTED UNDER 37 CFR §1.132

1. My name is Dr. Wolfgang-Reinhold Knappe, and I am over 18 years of age. I have personal knowledge of all facts I state in this Declaration, unless specifically indicated as being "on information and belief."

2. I am currently employed as Senior Scientist at Roche Diagnostics GmbH, (RDG) located in Mannheim Germany. I have been employed at RDG for 24 years including the time at Boehringer Mannheim GmbH. I studied chemistry from 1964 to 1967 at the University of Hamburg (intermediate diploma = "Vordiplom"), from 1967 to 1969 at the University of Heidelberg (B. Sc. (Chem.) = "Diplom"). I received a Ph. D. in chemistry ("Dr. rer. nat.") in 1971 at the University of Konstanz and qualified there for lecturing in chemistry in 1976. I joined Boehringer Mannheim GmbH in 1979, which in 1997 has been took over by RDG. Since then I have worked and I am still working in the development of test strips for different analytes in urine and blood including leukocytes (urine), erythrocytes (urine), urea, cholesterol, triglycerides, and glucose.

3. I am the Wolfgang-Reinhold Knappe listed as the sole inventor for above captioned United States Patent Application Serial No. 09/426,931 ("the present application").

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Atty. Docket BMID 9826 US

4. I have reviewed and am familiar with the present application, which discloses a spreading layer and wetting agent for their production and use in test strips. I have also reviewed the Office Action dated December 10, 2003 that has been received from the United States Patent Office in connection with the present application and the prior art references cited in the Office Action, specifically Good, et al. (US 6,194,224) and Dreyfus (US 2,063,987). I have carefully considered the positions stated in the Office Action that it would be obvious to use the oleoyl sarcosine wetting agents taught by Dreyfus in the test strips of Good et al. As stated in greater detail below, based upon experimental results, and my education, experience, and knowledge in the field, I do not believe that the reasoning set forth in the Office Action is supported by the evidence. Furthermore, I do not believe that the reasoning supports a rejection of the invention as claimed.

5. I personally supervised the following experiments, which compared the spreading ability of different sarcosinate derivatives absorbed into textiles. These experiments were performed in my laboratory located in Mannheim Germany.

6. Individual sheets (size DIN A 4) of Viledon-Fleece FO 2451/121 (obtained from Freudenberg, Weinheim (Germany)) were separately impregnated on a laboratory scale with a 0.125 % aqueous solution of one of the sarcosine derivatives listed in Table 1, below. The pH of the aqueous solution was adjusted to 7.0 with NaOH, if necessary. In all other aspects and manipulations, the different fleeces were treated and handled the same. Thereafter each impregnated sheet was dried.

Table 1

Fleece No.	Amino acid derivatives	Tradename	Supplier
1	N-lauroyl-sarcosine	Crodasinc L	Croda Chemicals Ltd. (GB)
2	N-oleoyl-sarcosine	Crodasinc O	Croda Chemicals Ltd. (GB)
3	Sodium N-cocoyl-sarcosinate	Nikkol Sarcosinate CN-30	Nikko Chemicals Co., Ltd. (JP)
4	Sodium N-myristoyl-sarcosinate	Nikkol Sarcosinate MN	Nikko Chemicals Co., Ltd. (JP)

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5	Sodium N-palmitoyl-sarcosinate	Nikkol Sarcosinate PN	Nikko Chemicals Co., Ltd. (JP)
6	Sodium N-methyl-N-cocoyl taurate	Adinol CT 95	Croda Chemicals Ltd. (GB)
7	Sodium N-methyl-N-oleoyl taurate	Geropon T 77	Rhône-Poulenc Chemie (F)
8	Sodium cocoyl L-glutamate	Amisoft CS-11	Ajinomoto Ltd. (JP)
9	Sodium myristoyl L-glutamate	Amisoft MS-11	Ajinomoto Ltd. (JP)

The following experiments were performed on the dried, impregnated fleeces:

Experiment 1

A section measuring approximately 1 cm x 3 cm was obtained from each impregnated Fleece Nos. 1-9. These impregnated fleece sections were laid on a polycarbonate foil. On to each fleece section, 10 µl of EDTA-venous blood was pipetted without touching the fleece with the pipette tip. For the sections obtained from Fleece Nos. 1 and 3 to 9 the drop of blood remained on the upper surface of the fleece section. However, for the section obtained from Fleece No. 2 the blood spontaneously spread between the fleece section and the foil. Subsequently, when each of the sections from Fleece Nos. 1 and 3-9 was touched with the pipette tip, blood spread between the fleece section and the foil.

Experiment 2

A section measuring approximately 8 cm x 8 cm was obtained from each impregnated Fleece Nos. 1-9. The different fleece sections were suspended on a ring so that the central portion of the underside of the fleece section did not touch any surface. On top of each fleece section, 10 µl of EDTA-venous blood was pipetted without touching the fleece with the pipette tip. For sections obtained from Fleece Nos. 1 and 3 to 9, the drop of blood remained on the upper surface of the fleece section. However, for the section obtained from Fleece No. 2 the blood formed a hanging

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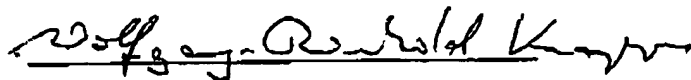
drop at the lower surface of the fleece. These results indicate the blood spread from the upper surface through the fleece to the lower surface.

7. For each of the Experiments listed above, the fleece impregnated with N-oleoyl-sarcosine exhibited significantly greater ability to spread or transport blood than the fleeces impregnated with the other sarcosine derivatives. The results are unexpected based upon the prior art references cited in the Office Action. In particular, Dreyfus (US 2,063,987) does not distinguish the different sarcosine derivatives based upon their blood spreading ability. To the contrary, Dreyfus specifically notes that "it is advisable in all cases to employ compounds which contain at least 12-16 and preferably 20 or more carbon atoms." (Dreyfus, col. 3, lines 8-10.) Thus, Dreyfus would not suggest to one skilled in the art to selected one sarconsine derivative over another.

8. Consequently, it has been demonstrated that fleece impregnated with N-oleoyl sarcosine exhibits significantly improved and unexpected properties for spreading blood through the fleece material. This result is neither taught nor suggested by Dreyfus or Good et al. It is believed that these references, considered either singly or together, do not make the claimed invention obvious.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: June 5th, 2003



Wolfgang-Reinhold Knappe